THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DANIEL J. BALBIERZ, JACK M. WALKER, JOSEPH R. THOMAS, ROBERT S. BLEY and KEVIN VAN BLADEL

Appeal No. 98-1936
Application 08/316,933[1]

ON BRIEF

Before MEISTER, ABRAMS and FRANKFORT, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final

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[1] Application for patent filed October 3, 1994. According to appellants, the application is a continuation-in-part of Application 08/000,274, filed January 4, 1993, now U.S. Patent No. 5,599,291, issued February 4, 1997.

rejection of claims 1 through 11 and 21 through 28, which are all

of the claims remaining in the application. Claims 12 through 20 and 29 through 37 have been canceled.

Appellants' invention is directed to an implantable or insertable medical device which is adapted to change shape or configuration, as a result of hydration, a change in temperature, and/or a combination thereof, subsequent to implantation or insertion. Independent claims 1, 5, 21 and 24 are representative of the subject matter on appeal and a copy of those claims, as reproduced from the Appendix to appellants' reply brief, is attached to this decision.

The sole prior art reference of record relied upon by the examiner in rejecting the appealed claims is:

Wiesner et al. (Wiesner) 5,348,537 Sept. 20, 1994
(Filed July 15, 1992)

An additional prior art reference applied by this panel of the Board in a new ground of rejection *infra* is:

Andersen 5,234,457 Aug. 10, 1993
(Filed Oct. 9, 1991)

Claims 1 through 11 and 21 through 28 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Wiesner.

Rather than reiterate the examiner's statement of the above-noted rejection and the conflicting viewpoints advanced by the

examiner and appellants regarding the rejection, we make reference to the final rejection (Paper No. 8, mailed November 12, 1996) and the examiner's answer (Paper No. 16, mailed December 23, 1997) for the examiner's reasoning in support of the rejection, and to appellants' brief (Paper No. 15, filed November 20, 1997) and reply brief (Paper No. 17, filed February 17, 1998) for appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellants' specification and claims, to the applied prior art reference, and to the respective positions articulated by appellants and the examiner. As a consequence of our review, we have made the determination which follows.

An anticipation under 35 U.S.C. § 102(b) is established

when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention. See RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 221 USPQ 385 (Fed. Cir. 1984). The law of anticipation does not require that the reference teach what the appellant is teaching or has disclosed, but only that the claim or claims on appeal on appeal "read on" something disclosed in

the reference, i.e., all limitations of the claim are found in the reference. See Kalman v. Kimberly Clark Corp., 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983).

Like appellants, we find that Wiesner fails to disclose or teach a medical device like that set forth in claims 1 through 11 and 21 through 28 on appeal. The examiner's position (answer, page 4) that the sealing element (15) of Wiesner somehow meets the structure of the medical device of appellants' claims 1 through 11 and 21 through 28 is simply not understood. The examiner has not read the language of any of the independent claims on appeal on the sealing element (15) of Wiesner and we see no way to do so either. The mere

fact that the polymeric sealing element (15) of Wiesner is swellable upon contact with an aqueous based liquid, such as that encountered when the catheter is inserted into a human body lumen, to attain a "first conformation" and was previously in a cured solid state defining an unswelled condition or a "second conformation," does not appear to us to meet the limitations of claims 1 through 11 and 21 through 28 on appeal.

In the language of claims 1 and 21 on appeal, we see nothing in Wiesner which teaches or discloses a medical device comprising a polymer structure (claim 1) or a structure (claim 21) that would ordinarily assume a first conformation and a hydrophilic polymer coated upon at least a portion of the structure, with the hydrophilic polymer being in a second conformation and having sufficient rigidity such that the polymer structure (claim 1) or the structure (claim 21) is held in the second conformation, wherein upon hydration of the hydrophilic polymer the polymer structure (claim 1) or the

structure (claim 21) assumes the first conformation. Likewise, in the language of claims 5 and 24 on appeal, we see nothing in Wiesner which teaches or discloses a medical device comprising a polymer structure of a first polymer material preconfigured into a first conformation (claim 5) or a structure of a first material preconfigured into a first conformation (claim 24) and a hydrophilic polymer material preconfigured into a second conformation, the respective mechanical strengths of the first material (claim 24) or first polymer material (claim 5) and the hydrophilic polymer material being such that the mechanical strength of the hydrophilic polymer material exceeds that of the first material (claim 24)

and the first polymer material (claim 5) sufficiently "so that the polymer structure" (claim 5) and the structure of claim 24 "is in the second conformation," wherein the hydrophilic polymer material "is adapted to lose its mechanical strength upon the occurrence of a triggering event" and upon loss of said mechanical strength, the device assumes the first conformation.

For the above reasons the examiner's rejection of claims 1 through 11 and 21 through 28 on appeal under 35 U.S.C. § 102(e) as being anticipated by Wiesner will not be sustained.

Pursuant to our authority under 37 CFR § 1.196(b), we enter the following new ground of rejection.

Claims 21 through 28 are rejected under 35 U.S.C. § 102(e) as being anticipated by Andersen.[2] More specifically, we note that Andersen discloses (in the language of claim 21 on appeal) a medical device for internal use in a patient, comprising a structure/stent that would ordinarily assume a first conformation (expanded configuration) and a hydrophilic polymer (col. 5, lines 3-5) coated upon at least a portion of the structure, with the hydrophilic polymer being in a second conformation and having

sufficient rigidity (when cured) such that the structure/stent is held in the second conformation (compact form), wherein upon increased temperature and hydration of the hydrophilic polymer the structure/stent assumes the first conformation or

[2] Andersen was cited and briefly discussed on page 5 of appellants' specification.

expanded configuration. Likewise, in the language of claim 24 on appeal, we note that Andersen discloses a medical device comprising a structure/stent of a first material preconfigured into a first conformation and a hydrophilic polymer material (col. 5, lines 3-5) preconfigured into a second conformation, the respective mechanical strengths of the first material and the hydrophilic polymer material being such that the mechanical strength of the hydrophilic polymer material (when cured) exceeds that of the first material sufficiently so that the structure/stent "is in the second conformation" (i.e., in a compact form), wherein the hydrophilic polymer material is adapted to lose its mechanical strength upon the occurrence of a "triggering event" and upon loss of said mechanical strength, the medical device assumes the first conformation or expanded form. Regarding claims 22, 23 and 25 through 28, we note that Andersen (col. 5, lines 3-5) refers to hydrophilic polymers such as polyvinyl alcohol based materials and gelatins which would inherently, upon hydration, soften and expand by from about 5% to 300%.

The decision of the examiner is reversed. A new ground of rejection has been entered pursuant to 37 CFR § 1.196(b).

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED, 37 CFR § 1.196(b)

JAMES M. MEISTER Administrative Patent Judge	)	
NEAL E. ABRAMS Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
CHARLES E. FRANKFORT Administrative Patent Judge	)	

Appeal No. 98-1936
Application 08/316,933

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APPENDIX

1. A polymeric medical device designed for internal use in a patient, comprising a polymer structure that would ordinarily assume a first conformation and a hydrophilic polymer coated upon at least a portion of the structure, the hydrophilic polymer being in a second conformation and having sufficient rigidity such that the polymer structure is held in the second conformation, wherein upon hydration of the hydrophilic polymer the polymer structure assumes the first conformation.

5. A polymeric medical device designed for internal use in a patient, comprising a polymer structure, the polymer structure comprising a first polymer material preconfigured into a first conformation and a second hydrophilic polymer material preconfigured into a second conformation, the first and second polymers having respective mechanical strengths, the mechanical strength of the second polymer material exceeding that of the first polymer material sufficiently so that the polymer structure is in the second conformation, wherein the second polymer material is adapted to lose its

mechanical strength upon the occurrence of a triggering event and upon loss of the mechanical strength of the second polymer, the device assumes the first conformation.

21. A medical device designed for internal use in a patient, comprising a structure that would ordinarily assume a first conformation and a hydrophilic polymer coated upon at least a portion of the structure, the hydrophilic polymer being in a second conformation and having sufficient rigidity such that the structure is held in the second conformation, wherein upon hydration of the hydrophilic polymer the structure assumes the first conformation.

24. A medical device designed for internal use in a patient, comprising a structure, the structure comprising a first material preconfigured into a first conformation and a hydrophilic polymer material preconfigured into a second conformation, the first material and the hydrophilic polymer having respective mechanical strengths, the mechanical strength of the hydrophilic polymer material exceeding that of the first material sufficiently so that the structure is in the second conformation, wherein the hydrophilic polymer

material is adapted to lose its mechanical strength upon the occurrence of a triggering event and upon loss of the mechanical strength of the hydrophilic polymer, the device assumes the first conformation.